

MAR 27 2014

Special 510 (k) – PATHFAST® cTnI Calibrator 1

510(k) SUMMARY

February 28, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K130603.

CONTACT:

Judi Smith  
Precision *for* Medicine  
2 Bethesda Metro Center, Suite 850  
Bethesda, MD 20814

on behalf of:  
Mitsubishi Chemical Medience Corporation  
2-8, Shibaura 4-chome, Minato-ku  
Tokyo, 108-8559 Japan

NAME OF DEVICE:

Trade Name:

PATHFAST cTnI Calibrator 1

Common/Classification Names:

Calibrator

Regulation Number:

862.1250

Product Code:

JIT

Class:

II

PREDICATE DEVICE:

PATHFAST cTnI Calibrator 1 which is  
supplied with the PATHFAST cTnI-II Test  
[K100130, 5/16/2011]

DEVICE DESCRIPTION:

INTENDED USE:

The PATHFAST® cTnI Calibrators are for calibration of the PATHFAST® system when used for the quantitative determination of cardiac Troponin I in human heparinized or EDTA whole blood and plasma.

PRODUCT DESCRIPTION:

The PATHFAST cTnI Calibrators are for calibration of the PATHFAST cTnI-II test performed on the PATHFAST instrument. PATHFAST cTnI-II test is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. Measurements of

## Special 510 (k) – PATHFAST® cTnI Calibrator 1

### 510(k) SUMMARY (cont.)

cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction.

Currently, PATHFAST cTnI Calibrators 1 and 2 are provided as lyophilized products of two vials each. Calibrator 1 consists of buffer only and Calibrator 2 consists of cTnI complex in buffer. Four vials of calibrator diluent also are provided for reconstitution of the calibrators. The diluent consists of an aqueous solution with 0.05% sodium azide. This Special 510(k) is being submitted for a change to a liquid Calibrator 1 formulation and a new dropper bottle container. There are no changes to PATHFAST cTnI Calibrator 2. As a result of elimination of the reconstitution step for PATHFAST cTnI Calibrator 1, the number of bottles of Calibrator Diluent is being reduced from four bottles to two bottles.

#### SUBSTANTIAL EQUIVALENCE:

The PATHFAST cTnI Calibrator 1 (liquid format) is substantially equivalent to the PATHFAST cTnI Calibrator 1 (lyophilized format) (K100130) in intended use and design. The similarities and differences are listed below.

**Substantial Equivalence Comparison Table**

<b>SIMILARITIES</b>		
<b>Item</b>	<b>PATHFAST cTnI Calibrator 1 Lyophilized (predicate device)</b>	<b>PATHFAST cTnI Calibrator 1 Liquid (Modified)</b>
FDA Submission Number	K100130	N/A
Intended Use	The PATHFAST® cTnI Calibrators are for calibration of the PATHFAST® system when used for the quantitative determination of cardiac Troponin I in human heparinized or EDTA whole blood and plasma.	No change
Fundamental Scientific Technology	cTnI concentration = 0 ng/mL. Provides zero analyte level for user calibration curve.	No change
Value Assignment	Primary calibrator, master calibrator, stock solution, working calibrator	No change
Instructions	Dispense approximately 100 µL of CAL-1 and CAL-2 in sample wells to load on PATHFAST.	No change

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**510(k) SUMMARY (cont.)**

<b>DIFFERENCES</b>		
<b>Item</b>	<b>PATHFAST cTnI Calibrator 1 Lyophilized (predicate device)</b>	<b>PATHFAST cTnI Calibrator 1 Liquid (Modified)</b>
Formulation	Lyophilized MES pH 6.0, lactose, and enzyme free human serum, DTT	Liquid saline solution with 0.05% sodium azide as preservative
Format	Lyophilized	Liquid
Calibrator 1 Container	Silicon-coated glass bottle with silicone rubber and plastic screw cap	Polypropylene droplet bottle with high density polyethylene nozzle and polypropylene screw cap
Calibrator Quantity	CAL-1 (1mL lyophilized×2vials) CAL-2 (1mL lyophilized×2vials) Calibrator Diluent (1mL×4 bottles)	CAL-1 (2mL liquid×1bottle) CAL-2 (1mL lyophilized ×2vials) (no change) Calibrator Diluent (1mL×2 bottles)
Instructions	Reconstitute each vial of CAL-1 and CAL-2 with one bottle (1mL) of Calibrator Diluent.	Reconstitute CAL-2 with one bottle (1mL) of Calibrator Diluent.

As part of the company's Design Control system, the following validation/verifications studies were performed.

- Formulation: assay sensitivity, accuracy, and precision, method comparison, sample type and matrix comparison
- Format: real time stability
- Container: elution and evaporation

The results of the validation and verification testing demonstrate that the modified PATHFAST cTnI Calibrator 1 met all specifications for the studies identified in the company's design control system Risk Analysis. Therefore, the modified PATHFAST cTnI Calibrator 1 is substantially equivalent to the current 510(k)-cleared PATHFAST cTnI Calibrator 1.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

March 27, 2014

MITSUBISHI CHEMICAL MEDIENCE CORPORATION  
C/O JUDI SMITH  
2 BETHESDA METRO CENTER  
SUITE 850  
BETHESDA MD 20814

Re: K130603  
Trade/Device Name: PATHFAST cTnl Calibrators  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: II  
Product Code: JIT  
Dated: March 18, 2014  
Received: March 19, 2014

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Courtney H. Lias -S**

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K130603

Device Name  
PATHFAST® cTnI Calibrators

**Indications for Use (Describe)**

The PATHFAST® cTnI Calibrators are for calibration of the PATHFAST® system when used for the quantitative determination of cardiac Troponin I in human heparinized or EDTA whole blood and plasma.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Ruth A. Chesler -S**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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